

51 Attorneys General Reach Consumer Protection Settlement with Boehringer Ingelheim Pharmaceuticals, Inc. Concerning Off-Label Promotion of Four Prescription Drugs

Delaware and the attorneys general of 49 other states and the District of Columbia have reached a settlement with Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") regarding alleged off-label marketing and deceptive and misleading representations made in BIPI's promotion of four of its prescription drugs: Micardis®, Aggrenox®, Atrovent®, and Combivent®.

The settlement resolves allegations that BIPI engaged in a course of trade or commerce that constitutes unfair, deceptive, or misleading practices, by making misrepresentations about the above-mentioned prescription drugs and by representing that the prescription drugs had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they did not have.

Specifically, the States allege BIPI: (1) misrepresented that its antiplatelet drug, Aggrenox®, was effective for many conditions "below the neck," such as heart attacks and congestive heart failure, and that it was superior to Plavix® without evidence to substantiate that claim; (2) misrepresented that Micardis® protected patients from early morning strokes and heart attacks and treated metabolic

syndrome; (3) misrepresented that Combivent® could be used as a first-line treatment for bronchospasms associated with chronic obstructive pulmonary disease (COPD); and (4) falsely stated that Atrovent® and Combivent® could be used at doses that exceeded the maximum dosage recommendation in the product labeling and that they were essential for treatment of COPD.

The settlement requires BIPI to ensure that its marketing and promotional practices do not unlawfully promote these prescription drug products. Specifically, BIPI will:

- Limit product sampling of the four drugs to health care providers whose clinical practice is consistent with the product labeling;
- Refrain from offering financial incentives for sales that may indicate off-label use of any of the four drugs;
- Ensure clinically relevant information is provided in an unbiased manner that is distinct from promotional materials; and
- Provide that requests for off-label information regarding any of the four drugs are referred to BIPI's Medical Division.

The settlement also requires BIPI to make payments to the states and the District Columbia that brought the case. For Delaware, about \$137,000 will go into the state's Consumer Protection Fund, which pays for the Delaware Department of Justice's work on consumer fraud and deceptive trade practice matters and other consumer-oriented investigations and legal actions.

Deputy Attorney General Gina Schoenberg led Delaware's efforts on this matter, with assistance from Consumer Protection Director Christian Douglas Wright and Deputy Attorney General James Vadakin.